

REMARKS

In the Office Action issued on April 27, 2010, the Examiner:

rejected claim 37 under 35 U.S.C. §112, second paragraph, as having insufficient antecedent basis;

rejected claim 37 under 35 U.S.C. §103(a) as being rendered unpatentably obvious by Healy (United States Patent No. 6,074,419) in view of Buck (United States Patent Application No. 2004/0006380);

rejected claim 37 under 35 U.S.C. §103(a) as being rendered unpatentably obvious by Buck in view of Bailey (United States Patent Publication No. 2001/0021872); and

rejected claim 37 under 35 U.S.C. §103(a) as being rendered unpatentably obvious by Makower (United States Patent No. 6,602,241) in view of Bailey.

The undersigned attorney has fully considered the Office Action and cited references and submits this Reply and Amendment in response to the Examiner's action. Applicants respectfully request reconsideration of the application for patent.

Amendments to the claims

Applicants have herein cancelled withdrawn claims 1 through 36.

Applicants have herein amended independent claim 37 to provide antecedent basis for the packaging material element.

This amendment to claim 37 is fully supported by the application as originally filed; no new matter has been introduced. Exemplary support is found in paragraph [0015].

New claims

Applicants have herein added new claims 38 through 47. Each of these new claims ultimately depends from independent claim 37 and is fully supported by the application as originally filed; no new matter has been introduced. Exemplary support is found in Figures 1A through 9 and in paragraphs [0039] through [0049].

Rejections under 35 U.S.C. §112

In order to comply with the requirements of the second paragraph of 35 U.S.C. §112, Applicants have herein amended claim 37 to provide proper antecedent basis for the packaging material element.

Applicants respectfully assert that this claim now fully complies with §112 and request withdrawal of this rejection of claim 37.

Rejections under 35 U.S.C. §103

Healy in view of Buck

The Examiner rejected independent claim 37 as being unpatentably obvious over Healy in view of Buck.

The Examiner asserts that Healy discloses “a stentless heart valve with indicia indicating the location of the device, the circumferential orientation, and the ascending and descending end/orientation” and “using the indicia to orient and deliver said valve into the heart.” The Examiner notes that Healy “fails to positively disclose the use of a delivering [sic] such a device via a catheter

delivery system.” To cure this defect, the Examiner asserts that delivering such a device via a catheter system is well known in the art and points to Buck as an example, noting that it teaches “a stent delivery system and associated method designed to verify the orientation of a stent within a delivery system.”

Based on these characterizations of the references, the Examiner concludes that “it would have been obvious to one of ordinary skill in the art at the time of invention to modify Healy, further in view of Buck, in order to 1) utilize the indicia ... and 2) to accurately deploy the device.”

Applicants respectfully assert that the Examiner's conclusion that the claimed method is obvious in light of these references is flawed at least because it is based on an incorrect determination of the differences between the prior art and the claimed subject matter.

The device claimed in Healy merely discloses visual markings on a root valve allowing a surgeon to modify the tissue valve during surgery by visually inspecting the valve outside of the patient and the delivery apparatus. The visual markings are adhered to the surface of the device and are not imageable markings. These non-imageable markings would not be visible if the valve were placed in a delivery apparatus.

Thus, even if combined with the “stent delivery system and associated method” taught by Buck, Healy cannot teach or suggest at least the following steps required by claim 37

- determining the orientation of the valve prosthesis within the delivery apparatus *relative to the distal end of the delivery apparatus* using the determined location of the imageable structure; and
- verifying that the determined orientation of the valve prosthesis is indicative of a delivery approach specified by indicia located on at

least one of the delivery apparatus, the valve prosthesis, and the packaging material thereof;

- wherein a determined orientation in which the orifice of the valve prosthesis is located closest to the distal end of the delivery apparatus such that the leaflet structure extends away from the orifice and away from the distal end of the delivery device is indicative of an ascending delivery approach, and
- wherein a determined orientation in which the second end of the valve prosthesis is located closest to the distal end of the delivery apparatus such that the leaflet structure extends away from the orifice and toward the distal end of the delivery device is indicative of a descending delivery approach.

Thus, Applicants respectfully submit that the the Examiner has mischaracterized the scope and content of the cited references in a manner that skews the determination of the differences between the claimed invention and the prior art. Neither Healy nor Buck, taken alone or in combination, teach or suggest all steps required by claim 37. Applicants respectfully request withdrawal of this rejection of the claims under 35 U.S.C. §103(a).

Buck in view of Bailey

The Examiner rejected independent claim 37 as being unpatentably obvious over Buck in view of Bailey.

The indicia taught by Buck do not indicate the orientation of the stent relative to the delivery apparatus. Rather, they are indicative only of the length of the stent within the delivery apparatus. Bailey also fails to disclose a step of determining the orientation of the disclosed stent relative to the delivery

apparatus using imageable elements.

Thus, even if combined with Bailey, Buck does not teach or suggest at least the following steps required by claim 37

- determining the orientation of the valve prosthesis within the delivery apparatus *relative to the distal end of the delivery apparatus* using the determined location of the imageable structure; and
- verifying that the determined orientation of the valve prosthesis is indicative of a delivery approach specified by indicia located on at least one of the delivery apparatus, the valve prosthesis, and the packaging material thereof;
- wherein a determined orientation in which the orifice of the valve prosthesis is located closest to the distal end of the delivery apparatus such that the leaflet structure extends away from the orifice and away from the distal end of the delivery device is indicative of an ascending delivery approach, and
- wherein a determined orientation in which the second end of the valve prosthesis is located closest to the distal end of the delivery apparatus such that the leaflet structure extends away from the orifice and toward the distal end of the delivery device is indicative of a descending delivery approach.

Thus, Applicants respectfully submit that the the Examiner has mischaracterized the scope and content of the cited references in a manner that skews the determination of the differences between the claimed invention and the prior art. Neither Buck nor Bailey, taken alone or in combination, teach or suggest all steps required by claim 37. Applicants respectfully request withdrawal of this rejection of the claims under 35 U.S.C. §103(a).

Makower in view on Bailey

The Examiner rejected independent claim 37 as being unpatentably obvious over Makower in view of Bailey.

Applicants respectfully assert that Makower fails to teach at least the following steps required by claim 37

- determining the orientation of the valve prosthesis within the delivery apparatus *relative to the distal end of the delivery apparatus* using the determined location of the imageable structure; and
- verifying that the determined orientation of the valve prosthesis is indicative of a delivery approach specified by indicia located on at least one of the delivery apparatus, the valve prosthesis, and the packaging material thereof;
- wherein a determined orientation in which the orifice of the valve prosthesis is located closest to the distal end of the delivery apparatus such that the leaflet structure extends away from the orifice and away from the distal end of the delivery device is indicative of an ascending delivery approach, and
- wherein a determined orientation in which the second end of the valve prosthesis is located closest to the distal end of the delivery apparatus such that the leaflet structure extends away from the orifice and toward the distal end of the delivery device is indicative of a descending delivery approach.

As described above, Bailey also fails to disclose these required steps.

Thus, Applicants respectfully submit that the the Examiner has

mischaracterized the scope and content of the cited references in a manner that skews the determination of the differences between the claimed invention and the prior art. Neither Makower nor Bailey, taken alone or in combination, teach or suggest all steps required by claim 37. Applicants respectfully request withdrawal of this rejection of the claims under 35 U.S.C. §103(a).

CONCLUSION

Applicants have fully responded to the rejections listed by the Examiner in the Office Action issued on April 27, 2010. A Notice of Allowability relating to all claims currently under consideration is appropriate and is respectfully requested.

Should the Examiner have any questions regarding this Reply and Amendment, or the remarks contained herein, the undersigned attorney would welcome the opportunity to discuss such matters with the Examiner.

Respectfully submitted,

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